REMARKS

Claims 1, 4, 6, 9-16 and 19-22 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Number 5,226,413 to Bennett et al. Claims 2, 3, 5, 7, 8, 17, and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bennett et al. in view of U.S. Patent Number 5,855,594 to Olive et al.

REJECTION UNDER 35 U.S.C. §102

Claims 1, 4, 6, 9-16 and 19-22 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Number 5,226,413 to Bennett et al. Reconsideration is respectfully requested.

Claims 1 and 15 are directed to a system and corresponding method that performs automatic capture verification. The system of Claim 1 includes autocapture means that detects the presence or absence of captured cardiac events in response to applied pacing pulses (i.e., it differentiates between successful paced events and unsuccessful (loss-of-capture) events). The system also includes control means that generates a visual representation of captured and loss-of-capture events, where the visual representation is based on whether each event is a captured cardiac event or a loss-of-capture event. Display means are provided to display the visual representation to a medical practitioner.

Thus, the claimed system determines whether each pacing pulse achieved capture or resulted in a loss of capture, and generates a corresponding visual representation based on that determination. In other words, Applicants' claimed invention distinguishes between two different types of paced events- captured events and loss-of-capture events, and identifies each event as one or the other.

In contrast, the Bennett et al. patent discloses a system that performs various tests, such as a capture threshold test. The Examiner contends that Bennett et al. teach identifying events including capture and loss of capture. However, what Bennett et al. actually disclose is that markers may be used to classify "sensed and paced events" (Col. 11, line 25). Nowhere do Bennett et al. disclose differentiating between

successful paced events and loss-of-capture events, nor do Bennett et al. provide a visual representation that uniquely identifies loss-of-capture events; rather, all events are either identified as paced or sensed events. Furthermore, Bennett et al. fails to disclose whether they label a loss-of-capture event as a paced event or a sensed event. Because Bennett et al. only disclose two makers, namely sensed events and paced events, loss-of-capture events are either improperly combined with successful capture events, or with non-paced, intrinsic events.

Thus, in order for a clinician to identify loss-of-capture events in the Bennett et al. system, the clinician would need to further analyze the data to manually distinguish successful paced events from loss-of-capture events, or to distinguish intrinsic events from loss-of-capture events. Bennett et al. do not provide an efficient system for identifying loss-of-capture events.

Thus, Applicants' claimed invention makes it easy for a clinician to quickly review patient data and identify whether any loss-of-capture events have occurred. In contrast, by labeling a loss-of-capture event as a "sensed" event or a "paced" event, Bennett et al. do not provide an efficient system for discriminating between loss-of-capture events and other events.

The Examiner identifies the Markowitz reference, incorporated by reference by Bennett et al., because it purportedly teaches that "events occurring in refractory periods are accepted as non-capture events". It is respectfully submitted that the Examiner is missing the point of Applicants' invention. Non-capture events are not synonymous with loss-of-capture events. Non-capture events are intrinsic events, and thus include premature beats, far-field sensing during a refractory period, and the like. Markowitz acknowledges this when he states that "[a]dditional events which may be displayed by the marker channel include premature beats such as ventricular premature beats 42, which occurs during a refractory period and is indicated by ventricular sense refractory marker 43 on the marker channel." (Col. 3, lines 62-66). It is clear that a premature beat is not the same thing as a loss-of-capture event: a premature beat is an intrinsic beat that occurs earlier than expected, while a loss-of-capture event is a pacing pulse that fails to capture the heart. Thus, the refractory event markers disclosed by

Markowitz are entirely different from Applicants' loss-of-capture visual representations. Nowhere does Markowitz teach or in any way suggest providing a specific marker to identify loss-of-capture events.

Therefore, neither Bennett et al. nor Markowitz teach or suggest a system that provides a visual representation to uniquely identify loss-of-capture events. Bennett et al. label events as either paced events or sensed events without differentiating between successful paced events and loss-of-capture events. Markowitz differentiates between refractory sensed events and other sensed events; however, Markowitz fails to differentiate between successful paced events and loss-of-capture events. Applicants' claimed invention distinguishes successful paced events (those that capture the heart) from unsuccessful paced events (loss-of-capture events) and generates different visual representations for each, thereby clearly identifying the loss-of-capture events. The prior art fails to teach or suggest such a system.

REJECTION UNDER 35 U.S.C. §103

Claims 2, 3, 5, 7, 8, 17, and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bennett et al. in view of U.S. Patent Number 5,855,594 to Olive et al. Reconsideration is respectfully requested in light of the following remarks.

As set forth above, Bennett et al. fails to teach or suggest a system that generates a visual representation to uniquely identify capture events as well as loss-of-capture events. Bennett et al. simply label events as either sensed or paced events, without any differentiation between successful and unsuccessful paced events.

Likewise, Olive et al. disclose a system that performs a capture threshold test. However, Olive et al. fail to teach or suggest providing event markers that differentiate between successful and unsuccessful paced events.

CONCLUSION

In light of the above remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

SJM CRMD LEGAL DEPT.

Respectfully submitted,

1/23/03

Derrick Reed, Reg. No. 40,138 Patent Attorney for Applicants

Pacesetter, Inc. 15900 Valley View Court Sylmar, CA 91392-9221 818/493-2200 818/362-4795 (fax)